



**<RULE>**

**<PREAMB>**

**<AGENCY TYPE='S'>ENVIRONMENTAL PROTECTION AGENCY**

**<CFR>40 CFR Part 180**

**<DEPDOC>[EPA-HQ-OPP-2009-0802; FRL-9350-4]**

**<SUBJECT>2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and  
degradates; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation amends the tolerances for residues of 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates in or on certain commodities discussed in this document. Loveland Products, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective June 1, 2012. Objections and requests for hearings must be received on or before July 31, 2012, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the <E T='02'>**SUPPLEMENTARY INFORMATION**</E> ).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2009-0802, is available either electronically through <http://www.regulations.gov> or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The

telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805). Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Andrew Bryceland, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6928; email address: [bryceland.andrew@epa.gov](mailto:bryceland.andrew@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**<HD1>I. General Information**

*<HD2>A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the

applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*<HD2>B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at

*[http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).*

*<HD2>C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0802 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 31, 2012. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0802, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online

instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- Mail: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

## <HD1>II. Summary of Petition For Tolerance

In the **Federal Register** of May 4, 2012 (77 FR 26477) (FRL-9348-3), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9F7626) by Loveland Products, Inc., 7251 W. 4th St., Greeley, Colorado 80634. The petition requested that 40 CFR 180.590 be amended by establishing tolerances for residues of the insecticide 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates, 2,6- DIPN and its metabolites and degradates, in or on potato, granules/flakes at 5.5 parts per million (ppm); potato, wet peel at 6.0 ppm; potato, whole at 2.0 ppm; cattle, fat at 0.2 ppm; cattle, meat at 0.02 ppm; cattle, meat byproducts, except fat at 0.02 ppm; goat, fat at 0.2 ppm; goat, meat at 0.02 ppm; goat, meat byproducts, except fat at 0.02 ppm; horse, fat at 0.2 ppm; horse, meat at 0.02 ppm; horse, meat byproducts, except fat at 0.02 ppm; milk, fat at 0.02 ppm; sheep, fat at 0.2 ppm; sheep, meat at 0.02 ppm and sheep, meat byproducts, except fat at 0.02 ppm. One comment was submitted. An anonymous commenter (EPA-HQ-OPP-2009-0802-0003) generally expressed opposition to EPA granting this tolerance specifically because “it is

time to stop allowing so many toxic chemicals to poison earth, which end up in American bodies causing cancer and other killing diseases and even in breast milk”. After conducting a comprehensive assessment of the data and information submitted by the petitioner, EPA has concluded there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of 2,6-DIPN. Thus, under the standard in FFDCA section 408(b)(2), a tolerance is appropriate. Based upon review of the data supporting the petition, EPA has modified the tolerance expressions such that only the parent need be included in the tolerance expression for livestock commodities. The reason for these changes are explained in Unit IV.C.

### **<HD1>III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates follows.

<HD2> *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of <HD2>

*B. Toxicological Endpoints*

1. Acute toxicity. While EPA's complete discussion and analysis of acute toxicity of 2,6-DIPN can be found in the **Federal Register** of August 8, 2003 (68 FR 47246) (FRL-7321-6), in summary, 2,6-DIPN is classified as Toxicity Category IV for the oral route of exposure (median lethal dose (LD<sub>50</sub>) > 5,000 milligrams per kilogram (mg/kg)).
2. Short- and intermediate-term toxicity. While EPA's complete discussion and analysis of short- and intermediate-term toxicity of 2,6-DIPN can be found in the **Federal Register** of August 8, 2003, a summary is provided here. The subchronic toxicity study submitted and reviewed suggests the endpoint selection (value/dose at which an effect was observed) is the 104 milligrams per kilogram per day (mg/kg/day) no observed adverse effect level (NOAEL) based on reduced body weight, weight gain, and food

consumption. Although the developmental toxicity study indicated a lower NOAEL (50 mg/kg/day) for the same toxicity, the maternal lowest observed adverse effect level (LOAEL) of 150 mg/kg/day is between the subchronic NOAEL of 104-121 mg/kg/day and the LOAEL of 208-245 mg/kg/day. The NOAEL of 50 mg/kg/day may have been appropriate for use in characterization of risks for the subpopulation of women of childbearing age; however, the response at 50 mg/kg/day in the developmental study was minimal, and the observations for toxic effects were more thoroughly documented in the subchronic study.

3. Chronic toxicity. EPA has established the reference dose (RfD) for 2,6-DIPN at 1 mg/kg/day. This RfD is based on results from the subchronic and developmental toxicity studies described in the **Federal Register** of September 1, 2006 (71 FR 52011) (FRL-8081-9). In support of these tolerances, the RfD remains unchanged.

4. Carcinogenicity. No new study results suggest that 2,6-DIPN is carcinogenic. See EPA's complete discussion and analysis in the **Federal Register** of August 8, 2003. Specific information on the studies received and the nature of the adverse effects caused by 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates as well as the NOAEL and the LOAEL from the toxicity studies are discussed in the final rule published in the **Federal Register** of August 8, 2003.

*<HD2>C. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference

values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates used for human risk assessment is discussed in Unit III. of the final rule published in the **Federal Register** of December 16, 2009 (74 FR 66574) (FRL-8798-5).

#### <HD2> D. *Exposure Assessment*

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates, EPA considered exposure under the petitioned-for tolerances as well as all existing 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates tolerances in 40 CFR 180.590. EPA assessed dietary exposures from 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates in food as follows:



i. Acute exposure. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. Chronic exposure. In conducting the chronic dietary exposure assessment anticipated residue and/or percent crop treated (PCT) were not used.

Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. In the case of 2,6-DIPN, the toxicity database did not indicate an acute endpoint, but the 100 mg/kg/day NOAEL from the subchronic toxicity study (rounded from 104 mg/kg/day) was used to evaluate potential acute dietary exposure as a conservative basis for risk characterization. Also, if the 50 mg/kg/day NOAEL from the developmental toxicity study had been used to establish an acute RfD, this choice would have been inconsistent with the use of the 100 mg/kg/day NOAEL since it implies that exposure to repeated daily doses at 100 mg/kg/day is potentially less hazardous than a single dose at 50 mg/kg/day. Given the minimal nature of the responses in the subchronic and developmental toxicity studies, and the fact that the NOAEL from the developmental study is only appropriate to the subgroup of females 13-49 years of age, using the 100 mg/kg/day RfD for the acute and chronic dietary assessments is more appropriate for assessing risk for other subgroups and the general population. Therefore, a conservative interpretation of these endpoints indicated the need for an acute dietary exposure

assessment. The 100 mg/kg/day endpoint was also interpreted as requiring a chronic dietary exposure assessment.

Acute and chronic dietary exposure assessments for 2,6-DIPN were conducted using the Dietary Exposure Evaluation Model software (DEEM™ version 1.30), which incorporates consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII, 1994-1996/1998).

For acute exposure assessments, individual 1-day food consumption data define an exposure distribution, which is expressed as a percentage of the acute population adjusted dose (aPAD) (for 2,6-DIPN, aPAD = 0.1 mg/kg/day). For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the commodity residue list is multiplied by the average daily consumption estimate for the food or food-form. The resulting residue consumption estimate for each food or food-form is summed with the residue consumption estimate for all other food or food-forms on the commodity residue list to arrive at the total estimated exposure. Exposure estimates are expressed as mg/kg body weight/day and as a percent of the 2,6-DIPN chronic population adjusted dose (cPAD) (0.1 mg/kg/day). These procedures are performed for each population subgroup.

EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. If quantitative cancer risk assessment is appropriate, cancer risk may be quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event.

If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized.

Based on the data summarized in Unit III.A., EPA has concluded that 2,6-DIPN does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iii. Anticipated residue and PCT information. EPA did not use anticipated residue and/or PCT information in the dietary assessment for 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. Dietary exposure from drinking water. Because 2,6-DIPN treatment of stored (i.e., post-harvest) potato occurs inside (in warehouses, for example), no concern from exposure through water is expected regarding acute and chronic dietary risk assessment. For this reason, the dietary risk assessment did not include drinking water values.

3. From non-dietary exposure. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates is not registered for any specific use patterns that would result in residential exposure.

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the

cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates to share a common mechanism of toxicity with any other substances, and 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at

<http://www.epa.gov/pesticides/cumulative>.

*<HD2>E. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There were no observed prenatal and postnatal effects.

3. Conclusion. Based on the risk assessments and in consideration of residue data, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of 2,6-DIPN, including its metabolites and degradates, within the existing tolerance limits resulting from post-harvest applications, undertaken in accordance with good agricultural practices and EPA-approved labeling, to potatoes. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. In arriving at this conclusion, EPA has retained the tenfold margin of safety in order to adequately account for potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children,

*<HD2>F. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. Acute risk. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates is not expected to pose an acute risk.

2. Chronic risk. There are no residential uses for 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates.
3. Short-term risk. Because no short-term adverse effect was identified, 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates is not expected to pose a short-term risk.
4. Intermediate-term risk. Because no intermediate-term adverse effect was identified, 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates is not expected to pose a intermediate-term risk.
5. Aggregate cancer risk for U.S. population. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, 2,6-DIPN is not expected to pose a cancer risk to humans.
6. Determination of safety. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates residues.

#### **<HD1>IV. Other Considerations**

##### *<HD2>A. Analytical Enforcement Methodology*

Loveland Products, Inc. has proposed a liquid chromatographic/ultraviolet (LC/UV) detection analytical method for enforcement of tolerances for residues of 2,6-DIPN in potatoes and potato peels. While tolerances are set for livestock commodities, no analytical method is being required for livestock commodities based on a re-evaluation of the cattle feeding study and the existing ruminant metabolism study which was conducted in goats at a feeding level two times the Maximum Reasonable Dietary Burden

(MRDB). The parent compound DIPN and the metabolites M27 and M29 were quantifiable in all edible livestock matrices. In the cattle feeding study DIPN was quantifiable at exaggerated feeding levels, and at the MRDB in fat. The results of the metabolism and feeding studies indicate that fat will likely have the highest residues of any of the livestock matrices, and USDA monitors fat for pesticide residues accessed 5/10/12). Therefore, the parent will be an adequate marker for misuse, particularly with regard to fat which is the commodity most likely to have residues and most likely to be monitored. Accordingly, the residue definition for the tolerance expression can be modified to include the parent compound only.

The method (entitled, "Liquid Chromatographic Analysis for the Determination of 2,6-Diisopropylnaphthalene (DIPN) in Potatoes and Liquid Chromatographic Analysis for the Determination of 2,6-

Diisopropylnaphthalene (DIPN) in Potato Peels" (Platte Report Number CARDC-1298-DIPN)) was used for the determination of residues of 2,6-DIPN in potatoes and potato peels.

The method includes instructions and chromatograms for analysis of samples of potatoes and potato peels. Briefly, samples are extracted with acetonitrile. The extracts are partitioned with hexane. The acetonitrile part is discarded. The hexane part is roto-evaporated to dryness. The residues are reconstituted in hexane and purified using a Florisil column. The residues are roto-evaporated to dryness and reconstituted in acetonitrile. The samples are filtered through Acrodisc® LC polyvinylidene difluoride (PVDF) 0.45 micrometer ( $\mu\text{m}$ ) filters and analyzed by high performance liquid chromatography (HPLC) with ultraviolet (UV) detection at 254 nanometers (nm) using a

Zorbax ODS column.

The validated limit of quantitation (LOQ) is 0.01 ppm for 2,6-DIPN in potatoes and 0.02 ppm in potato peels. The reported limits of detection (LODs) were 0.001 ppm for 2,6-DIPN in potatoes and potato peels. The method does not include instructions for confirmatory analysis. Method validation data for the LC/UV method demonstrated adequate method recoveries of residues of 2,6-DIPN. Potato samples were fortified with 2,6-DIPN at levels of 0.01 ppm, 0.02 ppm, 0.05 ppm, and 50 ppm. Samples were analyzed at the limit of quantitation of 0.01 ppm. Overall, recovery ranges (and CVs) from these matrices were 77.9-123.2 (13.9%) for 2,6-DIPN. Potato peel samples were fortified with 2,6-DIPN at levels of 0.02 ppm, 0.05 ppm, and 0.2 ppm. Samples were analyzed at the limit of quantitation of 0.02 ppm. Overall, recovery ranges (and CVs) from these matrices were 83.2-96.1 (5.3%) for 2,6-DIPN.

Acceptable independent laboratory validation is available for this method using potato and potato peel samples. As described in this unit, an adequate enforcement methodology (liquid chromatographic/ultraviolet detection analytical method) is available to enforce the tolerance expression for potatoes and potato peels only.

The radiovalidation data for HPLC/UV(CARDC-1298-DIPN) for the determination of residues of 2,6-DIPN in potatoes and potato peels adequately recovered residues of 2,6-DIPN from samples of whole potato and potato peels with the treatment of the active ingredient. Multiresidue testing for 2,6-DIPN showed that the multiresidue methods are not adequate for enforcement purposes since 2,6-DIPN was not recovered through any of the protocols.



The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

#### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates.

#### *C. Revisions to Petitioned-For Tolerances*

Time-limited tolerances for 2,6-DIPN are set to expire on May 18, 2012 (40 CFR 180.590). In consideration of whether or not the continued use of the active ingredient when used on potatoes would impose further risks to human health, EPA has reviewed newly submitted data/information multiresidue testing for 2,6-DIPN and radiovalidation of the analytical method and multiresidue testing method for determination of 2,6-DIPN in potato and potato peels as well as re-evaluated existing data/information in support of a

full tolerance without time limitations. Receipt of this information satisfied the conditions of registration.

In the previous time limited tolerance, EPA determined that an acceptable revised enforcement analytical method for 2,6-Diisopropylnaphthalene (2,6-DIPN) and two metabolites (M27 and M29) in livestock commodities must be submitted. EPA also determined that radiovalidation data for 2,6-DIPN and its metabolites (M27 and M29) must also be submitted. These data have already been generated and final reports of these studies are anticipated to be submitted to the Agency by or before December 2012. Although EPA has requested additional data, EPA has revisited its original decision that the tolerance expression include two of the metabolites in addition to the parent compound. Based on this re-evaluation, EPA has decided to limit the tolerance expression to DIPN only. Feeding studies demonstrate that DIPN is quantifiable in all animal commodities. The highest residues are found in fat, and residues in fat were quantifiable without use of exaggerated feeding studies. Fat is also the commodity most frequently monitored for tolerance violative residues. Accordingly, EPA concludes that limiting the tolerance expression to parent only will be appropriate as a tolerance level for monitoring compliance with label application instructions for DIPN (the basis on which the safety determination for this tolerance was made). (Memorandum from C. Ollinger EPA/OPP/HED to L. Hollis EPA/OPP/BPPD dated May 11, 2012).

## **V. Conclusion**

Therefore, the tolerances for residues of 2,6-Diisopropylnaphthalene (2,6-DIPN) and its metabolites and degradates, are amended, in or on potato, granules/flakes at 5.5 parts per million (ppm); potato, wet peel at 6.0 ppm; potato, whole at 2.0 ppm; cattle, fat at 0.2

ppm; cattle, meat at 0.02 ppm; cattle, meat byproducts, except fat at 0.02 ppm; goat, fat at 0.2 ppm; goat, meat at 0.02 ppm; goat, meat byproducts, except fat at 0.02 ppm; horse, fat at 0.2 ppm; horse, meat at 0.02 ppm; horse, meat byproducts, except fat at 0.02 ppm; milk, fat at 0.02 ppm; sheep, fat at 0.2 ppm; sheep, meat at 0.02 ppm and sheep, meat byproducts, except fat at 0.02 ppm.

Modification of the residue definition based on re-examination of existing data as described in Unit IV.A. and D., also require modification of the tolerance level. Residues in milk, skim milk, cream, meat, liver, and kidney will be below the limit of quantitation (LOQ) of 0.02 ppm. Therefore, the tolerance may be set at 0.02 ppm. Residues are likely to be quantifiable in fat. HED recommends a level of 0.2 ppm. This is based on the maximum residue of 0.095 from the 8.9 ppm feeding level (0.6x the MRDB) extrapolated to the 1x feeding level, (equal to 0.158 ppm) and rounded up to 0.2 ppm. The existing tolerances for DIPN residues on hog commodities may be revoked, since potatoes are no longer considered a major feed item for swine (memorandum from C. Ollinger (EPA/OPP/HED to L. Hollis EPA/OPP/BPPD dated May 11, 2012).

## **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001)

or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded

mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 16, 2012

Keith A. Matthews,

*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section 180.590, paragraph (a) is revised to read as follows:

**§ 180.590 2,6-Diisopropylnaphthalene (2,6-DIPN); tolerances for residues.**

(a) *General.* Tolerances are established for residues of the growth inhibitor 2,6-DIPN, including its metabolites and degradates, in or on the commodities in the following table.

Compliance with the tolerance levels specified in the following table is to be determined by measuring only 2,6-Diisopropylnaphthalene.

Commodity	Parts per million
Cattle, fat	0.2
Cattle, meat	0.02
Cattle, meat byproducts, except fat	0.02
Goat, fat	0.2
Goat, meat	0.02
Goat, meat byproducts, except fat	0.02
Horse, fat	0.2

Horse, meat	0.02
Horse, meat byproducts, except fat	0.02
Milk, fat	0.02
Potato, granules/flakes	5.5
Potato, wet peel	6.0
Potato, whole	2.0
Sheep, fat	0.2
Sheep, meat	0.02
Sheep, meat byproducts , except fat	0.02

\* \* \* \* \*



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